

### **Remarks**

Applicant appreciates the thorough examination of the present application as evidenced by the final Office Action dated June 2, 2004 (hereinafter, "Final Action") and the subsequent Advisory Action dated December 3, 2004. Claims 1, 2, 4-10, 15-18, 21-23, 26-35 and 39-44 are pending in the present application upon entry of the proposed amendments. Claims 3, 11-14, 19, 20, 24, 25, 32 and 36-38 have been canceled without prejudice or disclaimer. Claims 1, 4, 5, 15, 16, 23, 32-24 and 40 have been amended herein. New Claim 44 has been added. As will be discussed in further detail below, support for the claim amendments and new Claim 44 can be found in the specification and claims as originally filed, and thus, Applicant does not believe that any new matter is added by entry of these amendments and the new claim. Accordingly, Applicant respectfully requests entry of these amendments and new Claim 44.

Applicant further notes that in the Final Action, Claims 1, 2, 4-10, 14-18, 21-24, 26-35 and 39-43 stand finally rejected. In the Advisory Action, it is stated that the proposed amendments to Claims 1 and 23 raise new issues that would require further consideration and/or search, and they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. See Advisory Action, page 2. Applicant addresses below the concerns raised by the Examiner.

#### **I. Interview Summary**

As previously indicated, Applicant appreciated the opportunity during the telephonic interview on September 1, 2004 to discuss with the Examiner the issues presented in the Final Action. During the telephonic interview with the Examiner, the Applicant, Dr. Colin Brown, Applicant's representatives, Dr. Shawna Cannon Lemon and Dr. Lisa Brown, and Professor Donald Davies, patentee of cited patent U.S. Patent No. 5,258,175, addressed the rejections under 35 U.S.C. §§ 112, second paragraph, 102 and 103 presented in the Final Action and proposed claim amendments as discussed below. The Examiner indicated that the arguments and proposed amendments likely overcome the rejections made of record in the Final Action.

## **II. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1, 2, 4-10 14-18, 21 and 22 stand finally rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. *See* Final Action, pages 2-3. In order to expedite prosecution, Applicant has amended Claim 1 to delete the recitation "acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other," as suggested by the Examiner. Applicant has further amended Claims 15 and 16 to recite that the dextrin is present in the claimed amount that is expressed in terms of "weight to volume" of the composition. Support for this amendment can be found in the specification at page 7, line 22, among other places.

Accordingly, Applicant respectfully requests entry of these amendments, and respectfully request withdrawal of these rejections under 35 U.S.C. § 112, second paragraph.

## **III. Claim Rejections Under 35 U.S.C. § 102**

Claims 1, 2, 4-10 and 14-16 stand finally rejected as being allegedly anticipated by U.S. Patent No. 5,258,175 to Davies (hereinafter, "the Davies patent"). *See* Final Action, pages 3-4. In order to expedite prosecution, Applicant has amended claim 1 to recite that "the dextrin is present in an amount of from 2.5-18% weight to volume of the composition." As noted by Professor Donald Davies, the inventor of the invention presented in the Davies patent, during the telephonic interview, the Davies patent is directed to dextrin derivatives for use in treatment of paraquat poisoning. As further noted by Professor Davies, the Davies patent **does not** disclose compositions for reducing the incidence of adhesions in a body cavity comprising an **aqueous formulation** containing a polysaccharide dextrin in an amount effective to reduce said adhesions, wherein the dextrin is **unsubstituted** and contains more than 15% of polymers with a degree of polymerisation (DP) greater than 12, **and wherein the dextrin is present in an amount of from 2.5-18 % weight to volume of the composition** as recited in amended Claim 1.

Applicant has canceled Claim 14 and amended Claims 15 and 16 to depend from Claim 1.

Accordingly, Applicant respectfully submits that amended Claim 1, and claims that depend therefrom, are not unpatentable in view of the Davies patent, and respectfully requests withdrawal of these rejections.

#### **IV. Claim Rejections Under 35 U.S.C. § 103**

##### **A. Claims 1, 2, 4-10, 14-18, 21, 22 and 39-43**

Claims 1, 2, 4-10, 14-18, 21, 22 and 39-43 stand finally rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 5,587,175 to Viegas et al. (hereinafter, "the Viegas patent") in view of the Davies patent for reasons set forth in previously filed Office Actions. *See* Final Action, pages 4-5. Applicant respectfully disagrees with this assertion.

As noted above in Section I, the Davies patent does not disclose the compositions recited in the claims of the present application. As further pointed out to the Examiner during the telephonic interview, the Viegas patent is directed toward a film-forming polymer. *See* Viegas, Abstract and Claim 1. In particular, Viegas et al. proposes that combining a water-soluble film-forming polymer with an ionic polymer optionally in the presence of a latent counter-ion provides an admixture that is "capable of being gelled in situ." Col. 18, line 40. As previously noted by Applicant, a "film-forming polymer" typically refers to an aqueous solution that subsequently forms a **solid** through evaporation, freezing or through a chemical reaction. Consequently, one of ordinary skill in the art would not be motivated to combine the Davies patent (directed to distinct dextrin derivatives for use in paraquat poisoning) and the Viegas patent (directed to film-forming polymers) to arrive at the present invention. Moreover, combining the cited references does not provide the present invention as recited in amended Claim 1. For similar reasons, the combination of the Viegas patent and the Davies patent does not teach or suggest the products or kits recited in Claims 39 and 40-43, respectively.

Accordingly, Applicant respectfully submits that Claims 1, 2, 4-10, 15-18, 21, 22 and 39-43 are not unpatentable in view of the combination of the Viegas patent and the Davies patent, and respectfully requests withdrawal of these rejections.

**B. Claims 23, 24 and 26-35**

Claims 23, 24 and 26-35 stand finally rejected under 35 U.S.C. § 103 as allegedly being unpatentable over the Viegas et al. patent in view of U.S. Patent No. 4,886,789 to Milner (hereinafter, the "Milner patent") for reasons set forth in previously filed Office Actions. Applicant respectfully disagrees with this assertion.

As noted above, the Viegas patent is directed to a film-forming polymer. The Milner patent, which is directed to a method of peritoneal dialysis using a composition containing an osmotic agent comprising a glucose polymer mixture (*see* Abstract), **does not** supply the missing recitations to provide the method recited in Claim 23. In an effort to expedite prosecution, however, Applicant has amended Claim 23 to recite as follows:

23. A method of reducing the incidence of adhesions in a body cavity, comprising introducing into the body cavity a composition comprising an aqueous formulation further comprising a polysaccharide dextrin in an amount effective to reduce the incidence of said adhesions, wherein the dextrin is unsubstituted and the dextrin contains more than 15% of polymers with a degree of polymerisation (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other, and wherein the aqueous formulation is a solution in the body cavity and further remains in the body cavity for at least 2 days.

Applicant respectfully submits that the combination of the Viegas patent and the Milner patent does not teach or suggest the recitations of amended Claim 23.

Accordingly, Applicant respectfully submits that Claims 23, 26-31 and 33-35 are not unpatentable in view of the combination of the Viegas patent and the Milner patent, and respectfully requests withdrawal of these rejections.

**V. New Claim 44**

New Claim 44 recites "[t]he composition according to Claim 2, wherein the solution remains a solution in the body cavity." None of the cited references, alone or in combination, teach or suggest a composition wherein the solution remains a solution in the body cavity as recited in new Claim 44.

Accordingly, Applicant respectfully submits that new Claim 44 is allowable over the cited references for at least these reasons.

**VI. Entry of Proposed Amendments**

In addition to stating that the proposed amendments to Claims 1 and 23 raise new issues that would require further consideration and/or search, and they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal, the Advisory Action states the following:

To impart patentability to an otherwise obvious chemical composition, proportions of ingredients, must produce more than a mere difference in degree in the properties of the composition.

Advisory Action, page 2 (citation omitted).

Applicant respectfully submits that the compositions recited in the present claims are not obvious in view of the compositions described in the cited references for the reasons set forth above. For example, the cited references are directed to compositions and/or methods generally relating to ionic and substituted dextrin derivatives (Davies), an ionic polysaccharide, film-forming polymer (Viegas et al.) and peritoneal dialysis (Milner) and not the compositions as recited in the present claims. Accordingly, the applied standard of patentability is met by the present compositions.

In summary, the compositions of the present invention are effective for reducing the incidence of adhesions. The cited references are directed to compositions and/or methods generally relating to ionic and substituted dextrin derivatives (Davies), an ionic polysaccharide, film-forming polymer (Viegas et al.) and peritoneal dialysis (Milner). None of the cited references, alone or in combination, disclose the compositions as recited in the present claims or address, or even acknowledge, the problems solved by the claimed invention, particularly as presented in the amended claims presented herein.

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**VII. Conclusion**

In view of the foregoing amendments and remarks, Applicant respectfully submits that the Examiner's concerns have been addressed, and respectfully requests that all outstanding rejections to the claims be withdrawn. Applicant also respectfully requests that a Notice of Allowance be issued in due course. Any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

In the event that additional fees are necessary to allow consideration of this paper, such an extension is also hereby petitioned for under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully submitted,

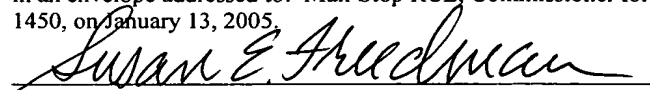


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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 13, 2005.



Susan E. Freedman

Date of Signature: January 13, 2005